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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BEISNER, WILLIAM H	

ART UNIT	PAPER NUMBER
1744	

DATE MAILED: 06/18/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/697,993	FISCHER, ANDREW H.	
	Examiner	Art Unit	
	William H. Beisner	1744	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *30 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/11/04;4/15/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Information Disclosure Statement

1. The information disclosure statements filed 11 March 2004 and 15 April 2004 have been considered and made of record.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is indefinite because the metes and bounds of the claim cannot be clearly determined. Specifically, it is not clear from the instant claim language whether or not the following elements are intended to be part of the positively claimed apparatus: "a cell sample"; "a sample port"; "a tissue cassette having attached thereto a filter"; "the reagents" and "the reagent port". The instant claim language appears to positively recite "a cell flow pathway" defined by "an inflow tube" and "a reagent flow pathway" defined by "a plurality of reagent delivery tubes". Note the claim merely recites that the cell flow pathway and inflow tube are intended "**for** delivering cell fragments from a cell sample to a sample port, the sample port being in fluid communication with a tissue cassette having attached thereto a filter". Nothing in this claim language clearly recites that the cell sample and/or sample port and/or cassette and/or filter are part of the claimed apparatus. The same holds true for the language "**for** delivering the

reagents to a reagent port in communication with the sample port". If the sample port, cassette, filter, etc. are intended to be part of the claimed apparatus, the claim language should clearly recite these elements are part of the claimed apparatus.

With respect to claim 2, the further limitation of claim 2 appears to be related to the tissue cassette and filter which have not been positively recited.

With respect to claims 3-6, these claims recite that a pressure is applied, however, claim 1 and claims 3-6 fail to positively recite a device for applying pressure. What structure is being further defined in view of this claim language?

With respect to claims 11-14 and 18, since claim 1 does not appear to positively recite the filter, cassette and/or sample port as part of the claimed device, it is not clear what further structure is defined in view of the positively recited elements of claim 1.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.

4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. Claims 1-7, 9-14, 18 and 19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Aeikens et al.(DE 2928790).

With respect to claim 1, the reference of Shiina et al. discloses a cell embedding device that includes a reagent flow pathway defined by a plurality of reagent delivery tubes (See Figure 1, elements 6-8). The tubes are provided in communication with a sample/reagent port (2) in communication with a filter (1) for collecting cells.

While the reference discloses filtering a cell sample on a filter (1) that is provided in communication with reagent delivery tubes, the reference does not disclose the use of a cell flow pathway or inflow tube for delivering cells from a cell sample to a port in communication with the filter.

The reference of Aeikens et al. discloses that it is known in the art to provide cells to a cell collection filter for tissue processing using a cell flow pathway (1) that includes a cell sample and an inflow tube for delivering the cells to a sample port (3).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the cell sample required of the primary reference using the system of the reference of Aeikens et al. for the known and expected result of providing an art recognized means for providing a cell sample to a filter for cell/tissue processing techniques.

With respect to claims 2-6, in the absence of positively recited structure further defining the device of claim 1, the combination of the references discussed above is considered to meet the instant claim language since the components of the modified primary reference are capable of

being automated and/or communicated with a device for providing a positive or negative pressure (See positive pressure pumps (63,73,83) and negative pressure pump (5).

With respect to claim 7, the tubes discloses by the reference of Shiina et al. is capable of delivering any of the listed reagents.

With respect to claims 9 and 10, the reference of Shiina et al. discloses the use of pumps (63,73,83) and valves (62,72,82) for controlling the flow of reagent to the filter. The specific valve employed would have been merely an obvious matter in design choice based on conventional valves known in the art, including tube-clamping valves which are desirable because they do not contact the contents of the tubes.

With respect to claims 11-14, the filter and tissue cassette have not been positively recited as part of the claimed device and the system of the modified primary reference would be capable of being provided in communication with a tissue cassette housing a removable filter.

With respect to claim 18, the sample port (2) is considered to be disposable.

With respect to claim 19, the device is fully automated as evidenced by controller (9) of the primary reference.

7. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Aeikens et al.(DE 2928790) taken further in view of Weiskopf (US 3,227,130).

The combination of the references of Shiina et al. and Aeikens et al. has been discussed above.

Claim 8 differs by reciting that reagent pathway includes a heated tube.

The reference of Weiskopf discloses that it is known in the art of tissue processing to include a tube heater (64) in the reagent pathway for improving and quickening the effects of the reagents on the tissue being processed (See column 3, lines 1-9).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagent pathway of the modified primary reference with a tube heater for the known and expected result of improving and quickening the effects of the reagent on the cells to be processed.

8. Claims 1-7, 9-11 and 13-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Aeikens et al.(DE 2928790) taken further in view of Williamson, IV et al.(US 5,817,032).

The combination of the references of Shiina et al. and Aeikens et al. has been discussed above.

With respect to claims 15-17, while the reference of Shiina et al. discloses the use of a vacuum source (5) and pressure gauge (4), the reference does not disclose the use of a waste container and/or a port on the waste container for the vacuum source and/or pressure gauge.

The reference of Williamson, IV et al. discloses that it is known in the art to employ a waste container with a port for connection to a vacuum source (See Figures 39 and 40).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to provide the vacuum configuration disclosed by the reference of Williamson, IV et al. to provide the vacuum required of the modified primary reference for the known and expected result of

providing an art recognized means for applying a vacuum to a filter while allowing the filtrate to be collected.

With respect to claim 1, if claim 1 is interpreted and/or amended to positively recite a tissue cassette and removable filter, the reference of Williamson, IV et al. discloses that it is known in the art to employ a tissue cassette (10) with a removable filter (14).

In view of this teaching, it would have been obvious to one of ordinary skill in the art to employ the tissue processing cassette disclosed by the reference of Williamson, IV et al. with the tissue processing system of the modified primary reference for the known and expected result of providing an art recognized means for collecting and processing tissue. Use of the cassette and filter disclosed by the reference of Williamson, IV et al. would facilitate the preparation of a sample for analysis in a microtome.

With respect to claims 2-6, in the absence of positively recited structure further defining the device of claim 1, the combination of the references discussed above is considered to meet the instant claim language since the components of the modified primary reference are capable of being automated and/or communicated with a device for providing a positive or negative pressure (See positive pressure pumps (63,73,83) and negative pressure pump (5).

With respect to claim 7, the tubes discloses by the reference of Shiina et al. is capable of delivering any of the listed reagents.

With respect to claims 9 and 10, the reference of Shiina et al. discloses the use of pumps (63,73,83) and valves (62,72,82) for controlling the flow of reagent to the filter. The specific valve employed would have been merely an obvious matter in design choice based on

conventional valves known in the art, including tube-clamping valves which are desirable because they do not contact the contents of the tubes.

With respect to claim 11, the filter (14) is removable from the cassette (10).

With respect to claim 13, the cassette includes cylindrical port (12).

With respect to claim 14, it would have been well within the purview of one of ordinary skill in the art to determine how to attach the sample port (2) of the reference of Shiina et al. with respect to the filter and cassette disclosed by the reference of Williamson, IV et al. See Figures 39 and 40 which would provide guidance on how to attached element (2) of the reference of Shinna et al. to filter/cassette of the reference of Williamson, IV et al.

With respect to claim 18, the sample port (2) is considered to be disposable.

With respect to claim 19, the device is fully automated as evidenced by controller (9) of the primary reference.

9. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Aeikens et al.(DE 2928790) and Williamson, IV et al.(US 5,817,032) taken further in view of Weiskopf (US 3,227,130).

The combination of the references of Shiina et al., Aeikens et al. and Williamson, IV et al. has been discussed above.

Claim 8 differs by reciting that reagent pathway includes a heated tube.

The reference of Weiskopf discloses that it is known in the art of tissue processing to include a tube heater (64) in the reagent pathway for improving and quickening the effects of the reagents on the tissue being processed (See column 3, lines 1-9).

In view of this teaching, it would have been obvious to one of ordinary skill in the art at the time the invention was made to provide the reagent pathway of the modified primary reference with a tube heater for the known and expected result of improving and quickening the effects of the reagent on the cells to be processed.

10. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Shiina et al.(JP 2000-146782) in view of Aeikens et al.(DE 2928790) and Williamson, IV et al.(US 5,817,032) taken further in view of Liu et al.(US 5,691,633).

The combination of the references of Shiina et al., Aeikens et al. and Williamson, IV et al. has been discussed above.

While the references of Shinna et al. and Williamson, IV et al. disclose the use of a filter for the cell sample, these references are silent as to the use of a polycarbonate filter.

The reference of Lui et al. discloses that the use of polycarbonate as a cell filter is well known in the art (See column 1, lines 27-37).

In view of this teaching and in the absence of a showing of criticality and/or unexpected results, it would have been obvious to one of ordinary skill in.the art at the time the invention was made to employ a polycarbonate filter in the system of the modified primary reference for the known and expected result of providing an art recognized means for filtering cells from a sample fluid for further analysis.

Conclusion

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to William H. Beisner whose telephone number is 571-272-1269. The examiner can normally be reached on Tues. to Fri. and alt. Mon. from 6:15am to 3:45pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert J. Warden can be reached on 571-272-1281. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

William H. Beisner
Primary Examiner
Art Unit 1744

WHB